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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/089,452

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/089,452	Applicant(s) REITER ET AL.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 41-55 is/are pending in the application.
- 4a) Of the above claim(s) 15-18, 20, 22-26 and 43-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 19, 21, 27-39, 41, 42 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 15-18, 20, 22-26 and 43-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendments filed March 6, 2006 and February 1, 2007 are acknowledged and have been entered. Claim 40 has been canceled. Claims 5-7, 11, 12, 14, 19, 21, 29, 32, 35, and 36 have been amended. New claim 55 has been added. Claims 1-39, 41-55 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 15-18, 20, 22-26 and 43-54 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 3, 2005.
4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude"

granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-14, 19, 21, 27-39, 41, 42 and 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 9-18 and 23 of U.S. Patent No. 7,129,053 (10/110,410). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods for detecting an infection of a mammal with an acid-resistant microorganism (can be acid-resistant bacterium), comprising incubating a stool sample with a receptor and permitting the complex to form and then detecting the antigen-receptor complex.

Applicants have asserted in the Remarks filed March 1, 2006, that “[T]o the extent that this rejection applies to the pending claims, Applicants will file a suitable terminal disclaimer once claims are indicated to allowable. It is noted,

however, that this rejection will be maintained until the PTO receives a properly filed terminal disclaimer.

7. Claims 1, 2, 6-12, 14, 29-39, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Svenson et al (WO 97/34149) or Mandrell et al (WO 99/49889).

Svenson et al discloses a method for detecting an infection (mycobacterial disease) in a mammal with an acid-resistant microorganism (*Mycobacterium*) comprising incubating a feces sample (stool sample), and that polyclonal antibodies or monoclonal antibodies directed against the mycobacterial antigen were used in an assay detecting the complexes formed (abstract; p. 3; p. 7; claims). ELISA and RIAs were used as a means of detection (p. 2; claims).

Mandrell et al discloses methods for testing for infection in a mammal with an acid-resistant microorganism using antibodies to detect the acid-resistant microorganism (p. 12). "The method of testing is described further wherein the sample is selected from the group consisting of poultry, swine and bovine carcasses, tissues and manure; animal production (farm) or processing water and equipment; biofilms on surfaces of animal carcasses, cells, tissues, production equipment or processing equipment; clinical samples (for example, feces or blood); fruit and vegetables; and fruit and vegetable irrigation and processing water." (p. 13) Mandrell et al discloses the use of polyclonal and monoclonal antibodies directed against proteins/antigens from acid-resistant microorganisms (claims).

The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a

distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed March 1, 2006 have been fully considered but they are not persuasive.

Applicants have asserted that Svenson teaches a method for diagnosing a microbacterial disease using mannans specific for this class of bacteria as antigens, which has nothing to do with the method for detecting an infection with acid-resistant microorganism using specific antibodies. The antibodies raised against the mannans of *Mycobacterium tuberculosis* will not work in an assay for detecting acid-resistant microorganism. However, it is not clear why Applicants have asserted that the prior art assay will not work, when the prior art is detecting acid-resistant microorganism infection in a mammal, the same as Applicants. The prior art is diagnosing mycobacterial disease in a patient caused by *Mycobacterium tuberculosis*; Applicants' specification and claims teach that *Mycobacterium tuberculosis* is a acid-resistant bacterium (i.e. acid-resistant microorganism). Detecting and diagnosing would appear to be the same.

With regard to Mandrell et al Applicants have asserted that Mandrell et al discloses antibodies against *Campylobacter jejuni* and *Campylobacter coli* and their general use in assays. There is no specific discussion on the methods used in the present invention. For example, the only place in the specification that mentions a specific use is on page 3, i.e., use of these antibodies in biosensors. In addition, general testing procedures are mentioned on page 7. Again, it would appear that the prior discloses the claimed invention, absent some evidence that the

claimed invention is not disclosed in Mandrell et al. The prior art is diagnosing mycobacterial disease or infection in a patient caused by *Campylobacter jejuni* and *Campylobacter coli* (see the claims); Applicants' specification and claims teach that these bacteria are acid-resistant bacterium (i.e. acid-resistant microorganism). Detecting and diagnosing would appear to be the same.

8. Claims 1-4, 6-12, 14, 30-33, 35, 37, 38, 42 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al (Lancet, 1992, 340:1194-1195).

Thomas et al discloses obtaining stool samples from mammals (humans) for detecting *H. pylori* infection (acid-resistant microorganism, bacterium) in the mammal (p. 1194). The faecal sample was suspended in PBS (p. 1194). The antigen-antibody complex was detected by ELISA (p. 1194).

The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed March 1, 2006 have been fully considered but they are not persuasive. With regard to Applicants' arguments that the ELISA of Thomas is used for antigens that have been obtained after having cultured the *H. pylori* from faeces and that one skilled in the art would not use Thomas' methods to detect for

infection, it is noted that the claimed method steps do not necessarily exclude some unrecited methods steps such as culturing the *H. pylori* from the faeces. Because Thomas' aim for the method is not the same as that specifically claimed does not necessarily mean that the invention is not taught or disclosed. If the method steps are the same or similar it would appear that the claimed invention is disclosed.

9. Claims 1-4, 6-12, 14, 29-39, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Larka et al (5932430).

Larka et al discloses a process for the determination of *H. pylori* (acid-resistant microorganism, bacterium) infection in a fecal specimen (stool sample) comprising contacting the sample with a diluent that has an antibody for *H. pylori* to form an antigen-antibody complex and then detecting the complex that has been formed (abstract; col. 2; claims). Larka et al discloses the use of both polyclonal, monoclonal antibodies as well as a plurality of antibodies, which generically refers to a polyclonal antibody and a mixture of monoclonal antibodies (col. 2). Larka et al discloses that the antibodies (receptors) can be immobilized (fixed) to a support such as filter paper, plastic beads and the like (col. 3). ELISA was used to monitor the complex formed (example 4, col. 6; col. 8).

The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed March 1, 2006 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., use of antibodies having different specificity and how to improve the sensitivity of the test) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The prior art discloses the use of both polyclonal and monoclonal antibodies as set forth in the instant claims.

Applicants have asserted that Larka et al fails to disclose the use antibodies for different antigens and provides no enabling teaching how to use monoclonal antibodies. However, a US Patent (i.e. Larka et al 5932430) is presumed valid and enabled. Since every patent is presumed valid (35 U.S.C. 282), and since that presumption includes the presumption of operability (*Metropolitan Eng. Co. v. Coe*, 78 F.2d 199, 25 USPQ 216 (D.C. Cir. 1935)), examiners should not express any opinion on the operability of a patent. Affidavits or declarations attacking the operability of a patent cited as a reference must rebut the presumption of operability by a preponderance of the evidence. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be

relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). When the patented document is used as a patent and not as a publication, the examiner is not restricted to the information conveyed by the patent claims but may use any information provided in the specification which relates to the subject matter of the patented claims when making a rejection under 35 U.S.C. 102(a), (b) or (d). *Ex parte Ovist*, 152 USPQ 709, 710 (Bd. App. 1963) (The claim of an Italian patent was generic and thus embraced the species disclosed in the examples, the Board added that the entire specification was germane to the claimed invention and upheld the examiner's 35 U.S.C. 102(b) rejection.)

10. No claims are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "N. M. Monfield", is written over the printed name.

N. M. Monfield

Primary Examiner

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NMM

May 7, 2007